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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,933	PARINS ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 55-60* is/are pending in the application.

4a) Of the above claim(s) *23-54 and 61-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 55-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/09/05, 04/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-22 and 55-60, drawn to a guidewire, classified in class 600, subclass 585.

   II. Claims 23-54 and 61-62, drawn to methods of making a guidewire, classified in class 29, subclass 844.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process wherein the steps comprise providing a solid core member having an integrally formed hollow tubular member at its distal end, and a coil member having proximal and distal ends; the coil member may be disposed along the distal end of the distal member such that it extends distally beyond the distal end of the core member; the tubular member can therefore be connected to the coil member to form the distal assembly, which extends distally beyond the distal end of the core member.

3. During a telephone conversation with James Wickhem on November 21, 2005 a provisional election was made without traverse to prosecute the invention of group I, claims 1-22 and 55-60. Affirmation of this election must be made by applicant in replying to this Office action. Claims 23-54 and 61-62 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

5. Claims 10-11, 16 and 57 are objected to because of the following informalities:

In regards to claim 10, at line 2, the limitation "crimping" renders the claim indefinite. From the limitations of claim 8 from which claim 10 depends, it is unclear whether the tubular member is connected to the core member through laser welding, laser diode soldering, or crimping.

In regards to claims 16 and 57, at line 3, "the distal end" should read --a distal end-- to avoid a potential lack of antecedent basis problem.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 13-16, 22, 55-56 and 58-60 are rejected under 35 U.S.C. 102(b) as being anticipated by De Toledo (US Patent No. 5,065,769).

In regards to claim 1, De Toledo discloses a guidewire 10, comprising:

a core member 42 having a proximal end and a distal end;

a tubular member 52 having a proximal end and a distal end, the tubular member 52 disposed about and connected to the distal end of the core member 42, the distal end of the tubular member 52 extending distally beyond the distal end of the core member 42; and,

a coil member (12, 14) connected to the tubular member 52 (see fig. 1).

In regards to claim 2, De Toledo discloses a guidewire 10 wherein the coil member (12, 14) includes a distal end and a proximal end, and wherein the distal end of the coil member (12, 14) extends distally beyond the distal end of the tubular member 52 (see fig. 1; column 3/lines 44-45, 51; column 4/line 9).

In regards to claim 3, De Toledo discloses a guidewire 10 wherein the proximal end of the coil member 52 is positioned proximate to or distal of the distal end of the core member 42 (see fig. 1).

In regards to claim 4, De Toledo discloses a guidewire 10 wherein the proximal end of the tubular member 52 fits over the distal end of the core member 42 (see fig. 1).

In regards to claim 5, De Toledo discloses a guidewire 10 that further includes a polymer sheath disposed about the coil member, the tubular member, and at least a portion of the core member.

In regards to claim 13, De Toledo discloses a guidewire 10 wherein the tubular member 52 has a circular cross section (see fig. 1).

In regards to claim 14, De Toledo discloses a guidewire 10 comprising:

a core member 42 including a proximal portion having a proximal end and a distal portion having a distal end; and

a distal assembly including a tubular member 52 having an inner surface adapted for connection to the distal portion of the core member 42, and an outer surface, and a coil member (12, 14) connected to the tubular member 52;

wherein the distal assembly is connected to the distal portion of the core member 42 such that a portion of the distal assembly extends distally beyond the distal end of the core member 42 (see fig. 1).

In regards to claim 15, De Toledo discloses a guidewire 10 wherein the distal assembly is connected to the distal portion of the core member 42 such that a portion of the tubular member 52 extends distally beyond the distal end of the core member 42 (see fig. 1).

In regards to claim 16, De Toledo discloses a guidewire 10 wherein the coil member (12, 14) includes a distal end and a proximal end, and wherein the distal end of the coil member (12, 14) extends distally beyond the distal end of the tubular member 52 (see fig. 1; column 3/lines 44-45, 51; column 4/line 9).

In regards to claim 22, De Toledo discloses a guidewire 10 wherein the tubular member 52 has a circular cross section (see fig. 1).

In regards to claim 55, De Toledo discloses a method of making a guidewire 10 comprising: an elongate core member 42 having a distal end and a proximal end; and distal assembly (12, 14, 52) means positioned proximate the distal end of the core member 42; wherein the distal assembly means (12, 14, 52) extends distally of the distal end of the core member 42 (see fig. 1).

In regards to claim 56, De Toledo discloses a method of making a guidewire 10 wherein the distal assembly means comprises a tubular apparatus 52 configured to fit over and secure to the distal end of the core wire 42 (see fig. 1).

In regards to claim 58, De Toledo discloses a method of making a guidewire 10 wherein the distal assembly means comprises a tubular section 52 configured to fit over and secure to the distal end of the core wire 42 and an integrally formed flexible section.

In regards to claim 59, De Toledo discloses a method of making a medical device 10 comprising: an elongated shaft 42 including a proximal portion having a proximal end and a distal portion having a distal end; and a distal assembly including a tubular member 52 and a ribbon or wire (12, 14) connected to and extending distally of the tubular member 52; wherein the distal assembly is connect to the distal portion of the elongated shaft 42 such that a portion of the distal assembly extends distally beyond the distal end of the elongated shaft 42 (see fig. 1).

In regards to claim 60, De Toledo discloses a method of making a medical device 10 wherein the ribbon or wire (12, 14) is a coiled ribbon or wire (see fig. 1; column 3/lines 44-52).

8. Claims 1-7, 13-17, 19, 22, 55-56, and 58-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Badera et al. (US Patent No. 5,040,543).

In regards to claim 1, Badera et al. disclose a guidewire, comprising: a core member 4 having a proximal end 16 and a distal end 8; a tubular member 6 having a proximal end and a distal end, the tubular member 6 disposed about and connected to the distal end of the core member, the distal end of the tubular member 6 extending distally beyond the distal end of the core member; and a coil member 2 connected to the tubular member 6 (see figs. 1-2).

In regards to claim 2, Badera et al. disclose a guidewire wherein the coil member 2 includes a distal end and a proximal end, and wherein the distal end of the coil member 2 extends distally beyond the distal end of the tubular member 6 (see fig. 1).

In regards to claim 3, Badera et al. disclose a guidewire wherein the proximal end of the coil member 2 is positioned proximate to or distal of the distal end of the core member 4 (see fig. 1).

In regards to claim 4, Badera et al. disclose a guidewire wherein the proximal end of the tubular member 6 fits over the distal end of the core member 4 (see fig. 1).

In regards to claim 5, Badera et al. disclose a guidewire wherein the proximal end of the coil member 2 fits over the distal end of the tubular member 6 (see fig. 1).

In regards to claim 6, Badera et al. disclose a guidewire further including a polymer sheath disposed about the coil member 2, the tubular member 6, and at least a portion of the core member 4 (see column 3/lines 45-49).

In regards to claim 7, Badera et al. disclose a guidewire wherein the polymer sheath is disposed over all of the core member 4 (see column 3/lines 60-64).

In regards to claim 8, Badera et al. disclose a guidewire wherein the tubular member 6 is connected to the core member 4 through mechanical fastening means (i.e. injection molding) (see column 4/lines 44-47).

In regards to claim 13, Badera et al. disclose a guidewire wherein the tubular member 6 has a circular cross section (see fig. 2).

In regards to claim 14, Badera et al. disclose a guidewire comprising: a core member 4 including a proximal portion having a proximal end and a distal portion having a distal end; and a distal assembly including a tubular member 6 having an inner surface adapted for connection to the distal portion of the core member 4, and an outer surface, and a coil member 2 connected to the tubular member 6; wherein the distal assembly is connected to the distal portion of the core member 4 such that a portion of the distal assembly extends distally beyond the distal end of the core member 4 (see figs. 1-2).

In regards to claim 15, Badera et al. disclose a guidewire wherein the distal assembly is connected to the distal portion of the core member 4 such that a portion of the tubular member 6 extends distally beyond the distal end of the core member 4.

In regards to claim 16, Badera et al. disclose a guidewire wherein the coil member 2 includes a distal end and a proximal end, and wherein the distal end of the coil member 2 extends distally beyond the distal end of the tubular member 6.

In regards to claim 17, Badera et al. disclose a guidewire further including a polymer sheath disposed about the coil member 2, the tubular member 6, and at least a portion of the core member 4 (see column 3/lines 45-49).

In regards to claim 19, Badera et al. disclose a guidewire wherein the distal assembly is connected to the core member 4 through mechanical fastening means (i.e. injection molding) (see column 4/lines 44-47).

In regards to claim 22, Badera et al. disclose a guidewire wherein the tubular member 6 has a circular cross section (see fig. 2).

In regards to claim 55, Badera et al. disclose a guidewire comprising: an elongate core member 4 having a distal end and a proximal end; and distal assembly means positioned proximate the distal end of the core member 4; wherein the distal assembly means extends distally of the distal end of the core member 4 (see figs. 1-2).

In regards to claim 56, Badera et al. disclose a guidewire wherein the distal assembly means comprises a tubular apparatus configured to fit over and secure to the distal end of the core wire (see fig. 2).

In regards to claim 58, Badera et al. disclose a guidewire wherein the distal assembly means comprises a tubular section configured to fit over and secure to the distal end of the core wire and an integrally formed flexible section (see fig. 1).

In regards to claim 59, Badera et al. disclose a medical device comprising: an elongated shaft 4 including a proximal portion having a proximal end and a distal portion having a distal end; and a distal assembly including a tubular member 6 and a ribbon or wire connected to and extending distally of the tubular member 6; wherein the distal assembly is connect to the distal portion of the elongated shaft 4 such that a portion of the distal assembly extends distally beyond the distal end of the elongated shaft 4 (see figs. 1-2).

In regards to claim 60, Badera et al. disclose a medical device wherein the ribbon or wire is a coiled ribbon or wire (see fig. 1).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 8, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Toledo ('769) in view of Palmer et al. (US Patent No. 6,544,231).

De Toledo discloses a guidewire 10, as described above, that teaches all the limitations of the claims except De Toledo does not teach the process of laser welding or soldering. However, Palmer et al. disclose a medical instrument wherein a coil is bonded to a metallic tubular structure through laser welding (see column 4/lines 16-18). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a connected apparatus similar to that of De Toledo with

a connecting process similar to that of Palmer et al. in order to tightly fuse metal elements together.

11. Claims 8, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badera et al. ('543) in view of Palmer et al. ('231).

Badera et al. disclose a guidewire, as described above, that teaches all the limitations of the claims except Badera et al. do not teach the process of laser welding or soldering. However, Palmer et al. disclose a medical instrument wherein a coil is bonded to a metallic tubular structure through laser welding (see column 4/lines 16-18). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a connected apparatus similar to that of Badera et al. with connecting process similar to that of Palmer et al. in order to tightly bond metal elements together.

12. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Toledo ('769) in view of Palmer et al. ('231) further in view of Cook et al. (US Patent No. 5,213,111).

De Toledo as modified by Palmer et al. discloses a guidewire, as described above, that teaches all the limitations of the claim except De Toledo as modified by Palmer et al. does not teach connecting the tubular member through crimping. However, Cook et al. disclose a guidewire wherein a coil member is connected to a core member through crimping (see column 3/lines 13-16). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guidewire similar to that of De Toledo as modified by Palmer et al. with a connecting

process similar to that of Cook et al. in order to hold the elements together in a friction-fit fashion.

13. Claims 12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badera et al. ('543) in view of Arenas et al. (US Patent No. 4,676,249).

Badera et al. disclose a guidewire, as described above, that teaches all the limitations of the claims except Badera et al. do not teach a tubular member comprising a hemispherical cross section. However, Arenas et al. disclose a guidewire 10 wherein a tubular member 19 comprises a hemispherical cross section (see fig. 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guidewire similar to that of Badera et al. with a tubular member similar to that of Arenas et al. in order to prevent forcing the tubular member (and core member) through the coils (see Arenas et al., column 4/lines 48-51).

14. Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over De Toledo ('769) in view of Fagan et al. (US Patent No. 6,113,557).

In regards to claim 57, De Toledo discloses a method of making a guidewire 10, as described above, that teaches all the limitations of the claims except De Toledo does not teach that the proximal end of the coil member fits over the distal end of the tubular member. However, Fagan et al. discloses a method of making a guidewire 100 wherein the proximal end of the coil 150 fits over the distal end of the tubular member 120 (see figs. 8-9). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method of making a guidewire similar to

that of De Toledo with a coil similar to that of Fagan et al. in order to track the distal end of the guidewire under radioscopy.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,063,935 to Gambale discloses a catheter guidewire with varying radiopacity at its distal end.

US Patent No. 5,217,026 to Stoy et al. discloses a guidewire with lubricious surface and method of fabrication.

US Patent No. 5,365,944 to Gambale discloses a guidewire extension with self-latching detachable connector.

US Patent No. 5,993,424 to Lorenzo et al. discloses a guidewire having a distal tip that can change its shape within a vessel.

US Patent No. 5,234,437 to Sepetka discloses a detachable pusher-vasocclusion coil assembly with threaded coupling.

US Patent No. 5,452,726 to Burmeister et al. discloses an intravascular guide wire and method for manufacture thereof.

US Patent No. 5,211,636 to Mische discloses a steerable infusion guide wire having state-of-the-art handling characteristics for ease of positioning a variety of catheters.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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